Grant Filed To Determine If the CeraShield Endotracheal Tube Can Reduce Hospital Acquired Infections

Approximately 1,000 Patient Clinical Study Planned in Mechanically Ventilated ICU Patients at Risk for Ventilator Associated Pneumonia

PARK CITY , UTAH , UNITED STATES , February 17, 2023 /EINPresswire.com/ -- N8 Biosciences today announced that Tbilisi Medical State University (TSMU), the leading medical school and research hub in Caucasus region, has filed a grant application with the UK Research and Innovation for funding of an approximately 1,000 patient clinical study to assess whether N8 Medical's CeraShield Endotracheal Tube (ETT) can prevent the most common, costly, and deadly hospital acquired infections in mechanically ventilated Intensive Care Unit (ICU) patients in Georgian hospitals. The UK funding opportunity is specifically limited to researchers from educational organizations in low- and middle-income countries (LMICs). The initial funding decision will be made in May at which time a full proposal will be required. A final funding decision will be made in November 2023.

The study protocol was developed in collaboration with Professor Michael Niederman (Weill Conrell Medical Center, NYC) who was a co-author on the 2017 international guidelines for managing Ventilator Associated Respiratory Infections (VARI), which includes Ventilator Associated Pneumonia (VAP). Professor Niederman is internationally recognized as a key opinion leader in the field of respiratory infections in the ICU. The Principal Investigator of the proposed study will be David Chakhunashvili, MD, PhD. Dr. Chakhunashvili is an assistant professor at TSMU, and a cooperative agreement manager of CDC projects at the National Center for Disease Control and Public Health (NCDC) under the Global Health Security Agenda. The study will enroll patients in three cohorts with the following conditions and diseases: trauma, cardiovascular diseases, and respiratory diseases who are expected to require mechanical ventilation in excess of 48 hours in the ICU.

"Ventilator Associated Pneumonia is a major healthcare concern in the LMICs, which includes the country of Georgia, which are mainly caused by multidrug resistant (MDR) gram-negative pathogens (most commonly Klebsiella pneumoniae, Pseudomonas aeruginosa and Acinetobacter spp.). The CeraShield ETT's ability to prevent biofilm fouling on the ETT is a promising alternative to preventing infection related complications. I believe that the results of

this study will benefit not only Georgia and all LMICs, but the countries of the developed world as well that are struggling to reduce the incidence of VAP and MDR pathogens, save patients' lives, and reduce the overall cost of care, "said Dr. Chakhunashvili.

Carl Genberg, N8 Medical's Chief Scientific Officer, and co-founder, said, "N8 is pleased to support this important study with supply of our biofilm resistant CeraShield Endotracheal Tubes. Biofilm growth on ordinary uncoated endotracheal tubes has been identified as a causative agent for developing VAP. When the history books are written, I believe that this study will be viewed as a seminal study showing that prevention is the best approach to reducing the incidence of antimicrobial resistant hospital-acquired infections. We look forward to the day in the near future when the use of the CeraShield ETT will be part of routine ICU care not only in Georgia, but worldwide. It is a solution that even poor countries can afford as its use will save money and it is available now. New drugs will take years to develop. In the meantime, many more people will die. As former FDA commissioner Dr. Scott Gottlieb has stated: "The best way to prevent a resistant microbe from becoming resistant is to prevent patients from becoming infected in the first place."

N8 Medical, LLC (N8 Medical) is a clinical-stage medical device company focused on commercializing medical devices that incorporate a novel class of active compounds called ceragenins.

The CeraShield ETT has been approved for use in Canada, Brazil, and other ex US countries. FDA has designated the CeraShield ETT as a "breakthrough device." It is not yet approved in the U.S.
Presentation at meeting of Pew Charitable Trust, September 2019

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